



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,015	02/17/2005	Noboru Yamaji	Q86324	5025
23373	7590	09/27/2006		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
			EXAMINER KOSAR, ANDREW D	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/525,015

Applicant(s)

YAMAJI ET AL.

Examiner

Andrew D. Kosar

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 and 13-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 11 and 13-17 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment / Arguments*

Applicant's amendments and arguments filed July 20, 2006 are acknowledged and have been fully considered.

Applicant has cancelled claims 1-10 and 12, thus rendering the rejections moot.

Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim 11 and new claims 13-17 are pending and have been examined on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 11 and 13-15** are rejected under 35 U.S.C. 102(b) as being anticipated by SKOV (PTO-892, 4/20/06).

The instant claims are generally drawn to a method of inhibiting articular cartilage extracellular matrix degradation (herein 'ACEM degradation') via administration of a HDACi.

The teachings of SKOV have been presented previously (*see* Office Action 4/20/06, page 13). SKOV teaches administration of FK228 administered to mice in 10% DMSO/saline (column 27, Tables 2A and 2B) at a dose of 0.5 mg/kg (column 27, lines 7-8). Applicant admits in the instant specification that FK228 was known in the art to have the requisite 100  $\mu$ M or less IC<sub>50</sub> value (page 13, instant specification, citing *Exp. Cell. Res. 1998*), thus if the compound were measured via the assay of instant claim 15, it would have an IC<sub>50</sub> of 100  $\mu$ M or less. Here, because one is administering the same compound at a dose within that which is disclosed in the instant specification (approximately 0.0001 to 100 mg, preferably 0.001 to 10 mg per dose, Instant specification page 15, lines 1-7), as 0.5 mg/kg is a dose of approximately 0.006 and 0.02

Art Unit: 1654

mg, as a mouse is approximately 12 to 40 g, practicing the method of Skov, administering the FK228 to a mouse, would inherently inhibit ACEM degradation.

**Claims 11 and 13-17** are rejected under 35 U.S.C. 102(b) as being anticipated by KAMMER (PTO-1449, 6/24/05).

The instant claims are presented *supra* and are further drawn to treating ACEM in arthroseitis, rheumatoid arthritis (herein 'RA') or osteoarthritis and to treating RA, arthroseitis or osteoarthritis caused by ACEM.

The teachings of Kammer have been presented previously (*see* Office Action 4/20/06, pages 11-12). Kammer teaches a method of treating RA with a histone hyperacetylating agent (claim 10). In looking to the specification for the preferred embodiments of the histone hyperacetylating agent usable in the method, the specification provides that HDACi are the preferred compounds (citing WO 97/11366), providing exemplary HDACi usable in the methods, including trichostatin A, SBHA, SAHA, apicidin (e.g. *Specification* pages 6-8) and specifically embodies in the claims (e.g. claims 3-9) trichostatin A, trapoxin A, FK228 (FR901228) and MS-275 (MS-27-275). As stated above, if measured, the FK228 (Kammer teaches that the compounds are preferably administered at 1  $\mu\text{mol/kg}$  to 50  $\mu\text{mol/kg}$ , more preferably at 22  $\mu\text{mol/kg}$  to 33  $\mu\text{mol/kg}$  for oral and i.v. administration, thus being of an overlapping, if not commensurate scope of the instantly disclosed preferred dosages. Further, in treating RA one would be treating/inhibiting the underlying conditions, e.g. ACEM. Additionally, Applicant admits in the instant specification that Kammer teaches treating RA with HDACi (spanning pages 6-7 of the instant specification).

Art Unit: 1654

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).


Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Andrew D. Kosar, Ph.D.  
Patent Examiner  
Art Unit 1654

  
Cecilia J. Tsang  
Supervisory Patent Examiner  
Technology Center 1600